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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,427	03/13/2001	Peter Andersen	670001-2002.5	2084

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FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/15/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/805,427

Applicant(s)

ANDERSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 12-20, 22, 24 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 21, 23 and 25-30 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14, 15, 20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Applicants' Request for Withdrawal of Finality, received 30September2003, paper#19, is acknowledged. Applicants indicate that an IDS, submitted 16July2003, was not considered in the Office Action, mailed 9September2003, paper#18, and that because of this omission, the finality of the Office Action should be withdrawn. Evidence of the IDS submission was in the photocopy of a receipt postcard stamped 16July2003 indicating that a PTO form 1449 was received.

The examiner has located the IDS and matched it with the application. It has been entered as paper#20.

2. Due to the nonconsideration of the IDS at the time of prior Office Action, mailed 9September2003, paper#18, the Office Action is hereby **VACATED**.

3. Applicants' Response to Office Action, received 29May2003, paper#16, is acknowledged. Claims 1, 9, 21, 23, and 25 have been amended.

4. Claims 1-31 are pending. Claims 12-20, 22, 24, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention (see Office Action, mailed 39December2002, paper#13).

5. Claims 1-11, 21, 23, and 25-30 are under consideration.

### **Rejections Withdrawn**

6. The objection to claims 23 and 25 because the claims are directed to nonelected inventions, is withdrawn in light of the claim amendments.

7. The rejection of claim 9 under 35 U.S.C. 101 because of the claimed recitation of a use, is withdrawn in light of the claim amendment.

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8. The rejection of claims 8, 9, 11, 25, and 27 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in response to applicants' arguments.

9. The rejection of claims 8, 9, 11, 25, and 27 under 35 U.S.C. 112, first paragraph, scope of enablement for a subunit vaccinating agent against *M. tuberculosis* for humans, is withdrawn in response to applicants' arguments.

### **Rejections Maintained**

10. The rejection of claims 1-11, 21, 23, 25-30 under 35 U.S.C. 112, second paragraph, indefiniteness of "derived", sequence identity of claimed polypeptides, is maintained.

The indefiniteness of "derived" is withdrawn in light of the claim amendments.

Applicants argue that examples of claimed fusion polypeptides are found in SEQ ID Nos:3 and 4 in the disclosure and that ESAT-6 and Ag85B sequences are well-known in the art. Therefore, there is sufficient disclosure to determine the metes and bounds of the claimed sequences.

The examiner has considered applicants' argument, but does not find it persuasive. While the disclosed sequences of fusion polypeptides are preferred embodiments, there is no restriction of the claimed fusion polypeptides to only these sequences. In addition, while the sequences of ESAT-6 and Ag85B may be known in the art, the claims are drawn to **any** T-cell epitope from each of ESAT-6 or Ag85B, without any guidance or restriction on which part of the sequences is utilized. Therefore, the claims remain indefinite.

11. The rejection of claims 8, 9, 11, 25, and 27 under 35 U.S.C. 112, first paragraph, scope of enablement for a vaccinating agent constructed from *M. tuberculosis* proteins which cross-protects against any/all other species of the genus *Mycobacterium*, is maintained for reasons put forth in the original rejection.

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Applicants argue that ESAT6 and Ag85B proteins are well-conserved within the species of the *Mycobacterium tuberculosis* complex.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons put forth in the original rejection, i.e., lack of any examples of the claimed cross-protection.

### **New Objection/Rejection Necessitated by Amendment**

#### **Claim Objections**

12. Claim 25 is objected to because of the following informalities: line 3, "composion" should be "composition". Appropriate correction is required.

#### **Claim Rejections - 35 USC § 112**

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method of preparation.

Claim 9 is a method of preparing a pharmaceutical composition. However, there is no listing of any method steps, only that the composition comprises the polypeptide of claim 1.

#### **Conclusion**

15. Claims 1-11, 21, 23, and 25-30 are finally rejected.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

  
RODNEY P SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

October 15, 2003